



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 24, 2017

Jamie N. Venable
Regulatory Affairs Specialist
Spartan Chemical Company, Inc.
1110 Spartan Drive
Maumee, OH 43537

Subject: PRIA Label and CSF Amendment – Change signal word, edit efficacy descriptors, revise precautionary statements, add Alternate CSF 1
Product Name: Steriphene II Brand Disinfectant Deodorant
EPA Registration Number: 5741-22
Application Date: June 14, 2017
Decision Number: 530458

Dear Ms. Venable:

The amended label and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSF(s):

- Basic CSF dated 01/23/2014
- Alternate CSF 1 dated 06/05/2017

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false

Page 2 of 2
EPA Reg. No. 5741-22
Decision No. 530458

or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Tom Luminello by phone at (703) 308-8075, or via email at luminello.tom@epa.gov.

Sincerely,

A handwritten signature in cursive script, appearing to read "Stacy Hardy".

for/

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch 2
Antimicrobials Division (7510P)

Enclosure: Stamped label

Master Label for Steriphene II Brand Disinfectant

Spartan Chemical Company, Inc.

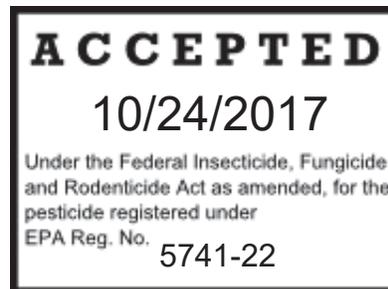
EPA Reg. No. 5741-22

Page 1 of 6

Revised 4/6/2017

Front Can Copy:

(Graphic showing product being sprayed on flush handle of toilet)



Steriphene II Brand Disinfectant Deodorant

Spring Breeze Fragrance

Clean Fresh Fragrance

Citrus Fragrance

Bactericidal / Tuberculocidal / Fungicidal* / Virucidal**

Effective against Antibiotic-Resistant Bacteria***

For Hospital, Institutional and Industrial Use

(NOTE TO EPA: The following bracketed text is optional)

[Kills Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella enterica and Mycobacterium bovis.

*Kills Trichophyton mentagrophytes (causes athlete's foot).

**Kills Hepatitis B Virus (HBV), Human Immunodeficiency Virus Type 1(AIDS Virus), Herpes Simplex Virus Type 2 (causes genital herpes) and Influenza A Virus on hard, nonporous inanimate surfaces.

***Kills Vancomycin-Resistant Enterococcus faecalis (VRE) and Methicillin-Resistant Staphylococcus aureus (MRSA)]

(NOTE TO EPA: -The use of the following bracketed phrases are optional:)

[-Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A Virus. This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza A and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

-This product has demonstrated effectiveness against Influenza A Virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A Virus.

-This product has demonstrated effectiveness against Influenza A Virus and is expected to

Master Label for Steriphene II Brand Disinfectant

Spartan Chemical Company, Inc.

EPA Reg. No. 5741-22

Page 2 of 6

Revised 4/6/2017

inactivate all influenza A viruses including Pandemic 2009 H1N1 Influenza A Virus (formerly called swine flu).

-Kills Pandemic 2009 H1N1 Influenza A Virus (formerly called swine flu).

-Kills Pandemic 2009 H1N1 Influenza A Virus]

ACTIVE INGREDIENTS:

Ethyl alcohol 64.000%

Ortho-Benzyl-para-chlorophenol 0.071%

Ortho-Phenylphenol 0.051%

INERT INGREDIENTS: 35.878%

TOTAL 100.000%

This Product contains sodium nitrite

EPA Reg. No. 5741-22

EPA Est. No. 33595-MO-2

<p>Keep Out of Reach of Children CAUTION: PRECAUCIÓN See rear panel for additional precautions.</p>
--

NET CONTENTS: 15 oz./425 g.

Master Label for Steriphene II Brand Disinfectant

Spartan Chemical Company, Inc.

EPA Reg. No. 5741-22

Page 3 of 6

Revised 4/6/2017

Back Side Can Copy:

(This product) (Product name) is for use on hard, nonporous surfaces in (hospitals), (schools), (hotels), (office buildings), (industrial plants), (funeral homes), (laboratories), (prisons and jails), and (other) (medical), (commercial), (institutional or industrial facilities where a sanitary environment is important).

Use on (bathroom and locker room fixtures), (tables), (countertops), (furniture), (doorknobs), (walls), (sinks), (telephones), (floors), (racks), (carts) and (wastebaskets).

(NOTE TO EPA: The following bracketed text is optional)

[(When used as directed,) (Steriphene II Brand Disinfectant) (This product) is effective against the following microorganisms at 5 minutes:

Bacteria:

Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella enterica

***Fungi:**

Trichophyton mentagrophytes (causes athlete's foot).

****Viruses:**

Human Immunodeficiency Virus Type 1(AIDS Virus), Herpes Simplex Virus Type 2 (causes genital herpes), Influenza A on hard, nonporous inanimate surfaces.

(When used as directed,) (Steriphene II Brand Disinfectant) (This product) is effective against the following microorganisms at 10 minutes:

Bacteria: Mycobacterium bovis

Viruses: Hepatitis B Virus (HBV)

*****Antibiotic-Resistant Bacteria:**

Vancomycin-Resistant Enterococcus faecalis (VRE),
Methicillin-Resistant Staphylococcus aureus (MRSA)]

This product is not be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

General Precautions and Restrictions

Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application. Following application as a spray, do not enter or allow others to enter the treated area until the sprays have dried.

Master Label for Steriphene II Brand Disinfectant

Spartan Chemical Company, Inc.

EPA Reg. No. 5741-22

Page 4 of 6

Revised 4/6/2017

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Clean all surfaces prior to disinfection.

5 Minute Contact Time:

Bacteria: Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella enterica

Fungi: Trichophyton mentagrophytes

Viruses: Human Immunodeficiency Virus Type 1(AIDS Virus), Herpes Simplex Virus Type 2 (causes genital herpes), Influenza A Virus on hard, nonporous inanimate surfaces

10 Minute Contact Time:

Bacteria: Mycobacterium bovis

Viruses: Hepatitis B Virus (HBV)

*****Antibiotic Resistant Bacteria:** Vancomycin-Resistant Enterococcus faecalis (VRE), Methicillin-Resistant Staphylococcus aureus (MRSA)

Disinfection and Deodorization: Shake well. Hold can 6 to 8 inches from surface and apply in a uniform moist film. Treated surfaces must remain wet for time indicated on the label. Allow to air dry or wipe off.

Tuberculocidal Activity: Steriphene II Brand Disinfectant is tuberculocidal under the above conditions in 10 minutes at 68°F (20°C).

* KILLS HBV AND HIV ON PRE-CLEANED ENVIRONMENTAL

SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Hepatitis B virus (HBV) and human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV and HIV-1 ON SURFACES OR OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

- 1. Personal Protection:** Clean up must be done wearing protective latex gloves, gowns, masks and eye protection.
- 2. Cleaning Procedure:** Blood or body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.
- 3. Contact Time:** Leave surfaces wet for 5 minutes for HIV-1. Leave Surfaces wet for 10 minutes for HBV.

Master Label for Steriphene II Brand Disinfectant

Spartan Chemical Company, Inc.

EPA Reg. No. 5741-22

Page 5 of 6

Revised 4/6/2017

4. Disposal of Infectious Material: Contaminated cleaning materials, blood and other body fluids must be autoclaved and/or disposed of according to local regulations for infectious waste disposal.

NOTE: Make sure valve opening is pointed in the direction of intended spray. Do not use on varnished wood or rayon fabrics. Steriphene II Brand Disinfectant Deodorant deodorizes at the source by killing the germs that cause malodors. This product is not intended for use as a general space spray air freshener.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: PRECAUCIÓN: Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If on skin or clothing:	-Take off contaminated clothing. -Rinse skin immediately with plenty of water for 15-20 minutes. -Call a poison control center or doctor for treatment advice.
24 HOUR MEDICAL EMERGENCY NUMBER: 888- 314-6171 Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

PHYSICAL OR CHEMICAL HAZARDS

Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.

Master Label for Steriphene II Brand Disinfectant

Spartan Chemical Company, Inc.

EPA Reg. No. 5741-22

Page 6 of 6

Revised 4/6/2017

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store in original container in areas inaccessible to small children.

Pesticide Disposal: Non-refillable container. Do not reuse empty container. Replace cap and discard in trash or offer for recycle, if available. Do not incinerate or puncture.

SPARTAN CHEMICAL COMPANY, INC. 1110 Spartan Drive, Maumee, Ohio 43537

Questions? 800-537-8990/ www.spartanchemical.com

(NOTE TO EPA: The following is an optional phrase:)

Fax On Demand Material Safety Data Sheet: 888-383-4666, No. (XXXX)